IVDR Webinar 2020-04-16 10.00 – 11.00

- Fundamentals you need to know
- Latest updates
- How to prepare

QAdvis

Presentation of the speaker – Anna-Karin Areskog

Senior Quality and Regulatory Consultant

Experiences within

- QA Manager
- IVDD and MDD
- GMP, ISO13485, QSR 21CFR 820
- Internal and external audits

Presentation of the speaker - Emma Axelsson

- Senior quality and regulatory consultant for medical devices and in vitro diagnostics
- Quality and Regulatory Manager medical device company
- Quality management system (ISO 13485:2016)
- MDD/MDR and IVDD/IVDR

QAdvis – Key competence areas

QMS In-the-cloud

Turn Key QMS
Digital Signatures
Efficient and Lean

System Development

Product Software Validation
Computer Systems Validation
Risk Management
Verification and Validation
Process Validation

European Authorised Representation

Providing European representation for non-EU MedTech companies
Active member of EAAR (European Association of Authorized Reps)

Training/Courses

CE-Marking, MDR, IVDR
ISO 13485 & QSR & MDSAP
IEC 62304 & IEC 82304-1
IEC 60601-1
IEC 62366-1
Risk Management
And more…

Agile, Lean and Six Sigma

Training and consulting in cooperation with US partner

QA&RA/Clinical Consulting

Interim Management, Expert Advise
Audits/Mock audit/Due Diligence
Warning Letters, Compliance Projects
PMA, 510k, CE-Marking, Tech Files
Global Regulatory Support
Vigilance, Recalls, PMS
Clinical Evaluation and Clinical Studies

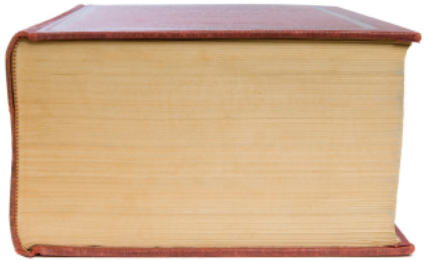
BACKGROUND MDR AND IVDR

QAdvis

Background

- MDD, AIMDD and IVDD old
- Technological and scientific development
- Different interpretations in Member States
- Scandals
- Product traceability

Background



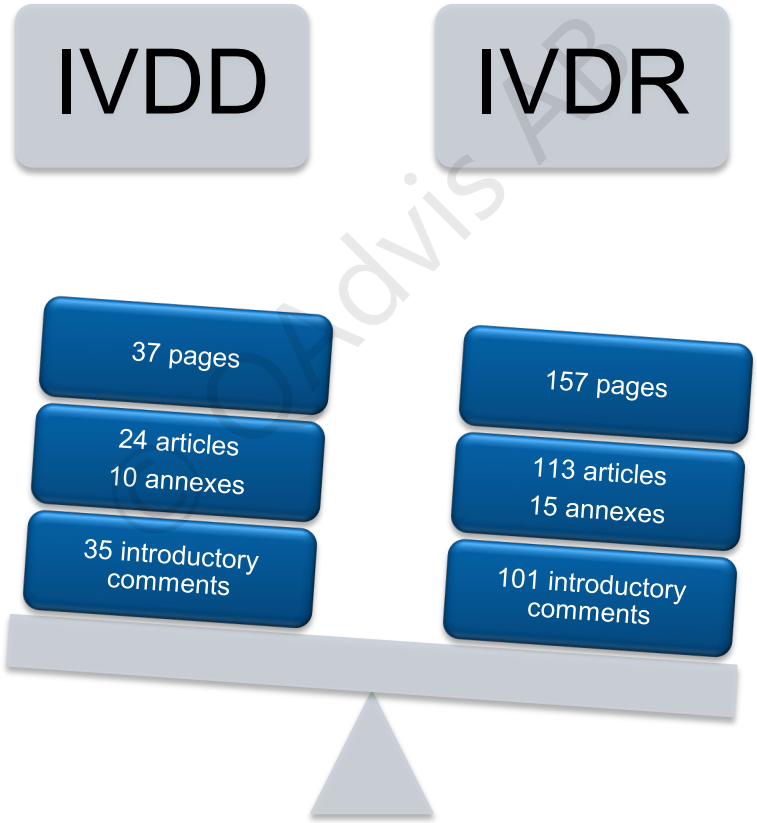
- Directives
  - AIMDD
    (90/385/EEG, LVFS 2001:5)
  - MDD
    (93/42/EG, LVFS 2003:11)

  MDR 2017/745

- Directive
  - IVDD
    (98/79/EG, LVFS 2001:7)

  IVDR 2017/746

Overview



QAdvis

IN VITRO DIAGNOSTIC REGULATION (IVDR)

QAdvis

Economic operator

- Manufacturer, importer, distributor and authorized representative
- Responsibilities and authorities
- Control of each other
- Eudamed
- Importers – name and address on device, packaging or accompanying documentation

(MDR/IVDR Article 10, 11, 13, 14)

QAdvis

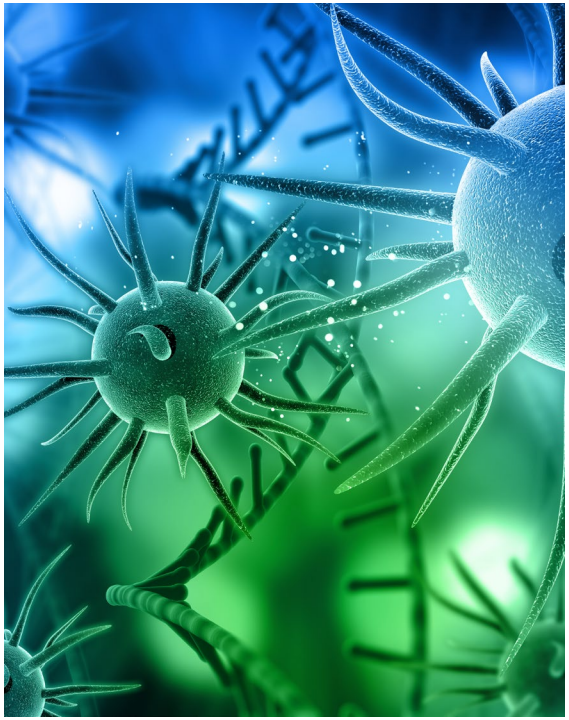
Person Responsible for Regulatory Compliance (PRRC)

Manufacturer shall have available within their organization at least one person responsible for regulatory compliance.

“The person responsible for regulatory compliance shall suffer no disadvantage within the manufacturer's organization in relation to the proper fulfilment of his or her duties, regardless of whether or not they are employees of the organization.”

(MDR/IVDR Article 15)

General obligations of manufacturers



Requirements on

- QMS
- Manufacturing and design
- Clinical evaluations (MDR) / Performance evaluation (IVDR)
- UDI system
- Risk management
- Technical documentation and DoC
- Vigilance
- Post market surveillance system

(MDR / IVDR Article 10)

TECHNICAL DOCUMENTATION

QAdvis

Intended purpose

- Shall be defined by the manufacturer
- Basis for classification
- The purpose for which a device is intended, according to;
  - Label
  - Instructions for use
  - Promotional or sales materials
  - Statements
  - As specified by the manufacturer in the clinical evaluation

(IVDR Article 2(12))

QAdvis

Technical Documentation - Overview

- General Safety and Performance Requirements (GSPR) (Annex I)
- Technical Documentation (Annex II)
- Technical Documentation on PMS (Annex III)
- Declaration of Conformity (DoC) (Annex IV)
- Performance evaluation, performance studies and post-market performance follow-up (Annex XIII)
- Interventional clinical performance studies and certain other performance studies (Annex XIV)

(IVDR Annex I, II, III, IV, XIII, XIV)

QAdvis

Technical Documentation – Annex II

1. Device description and specification
2. Information to be supplied by the manufacturer
3. Design and manufacturing information
4. General safety and performance requirements
5. Benefit-risk analysis and risk management
6. Product verification and validation

General Safety and Performance Requirements (GSPR)

- Change from IVDD Essential Requirements (ER) to General Safety and Performance Requirements (GSPR)
- Checklist recommended
- Method of compliance
- Reference to evidence of compliance

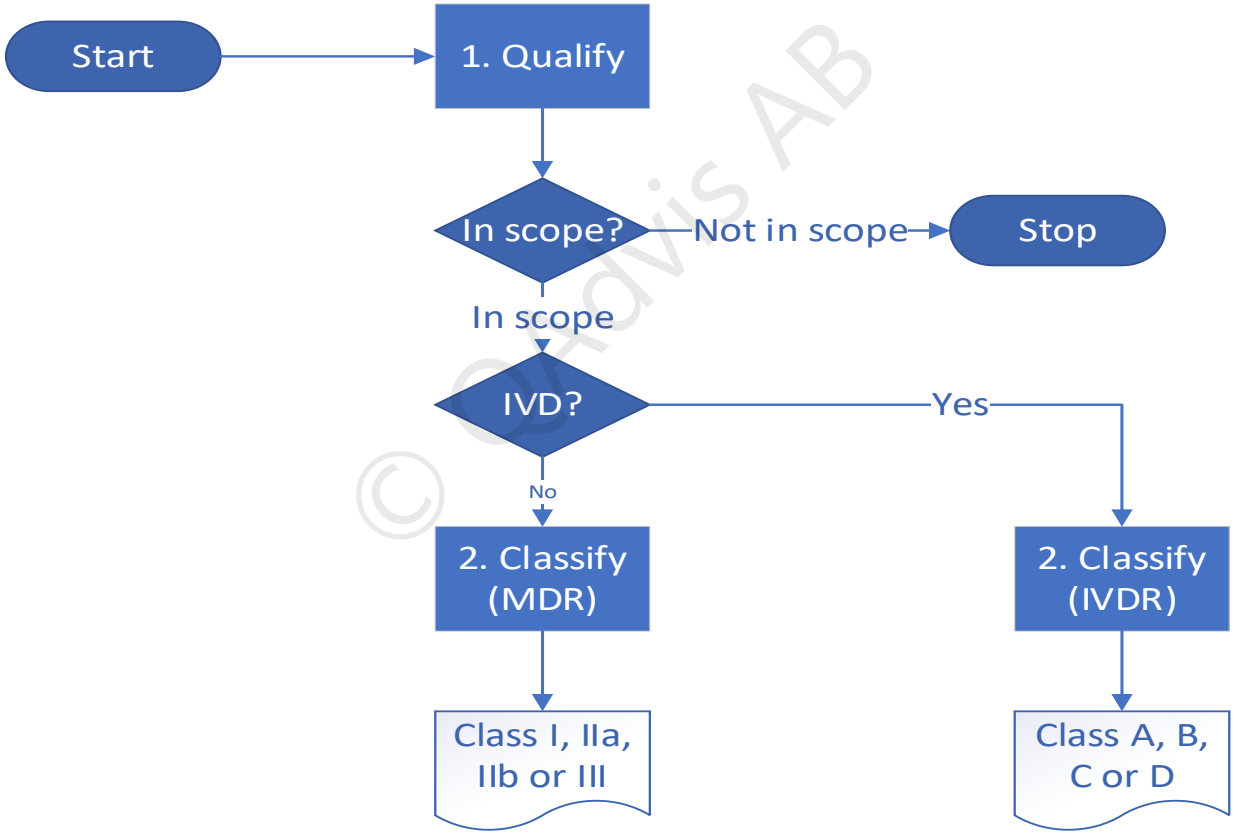
(IVDR Annex I)

General Safety and Performance Requirements (GSPR)

- General Requirements (GSPR 1-8)
- Requirements regarding Performance, Design and Manufacture (GSPR 9-19)
- Requirements regarding information supplied with the device (GSPR 20)

(IVDR Annex I)

Qualification and classification

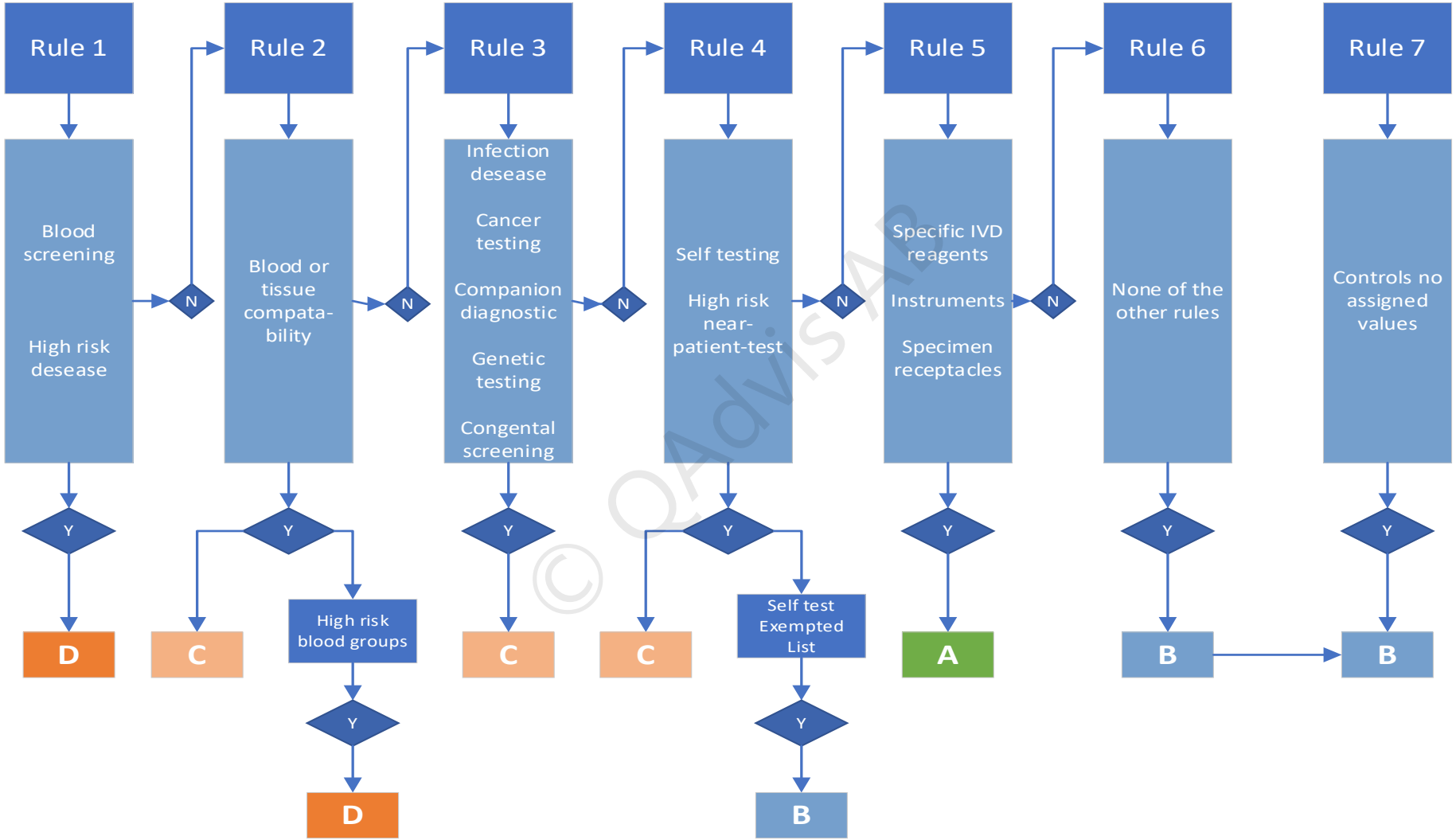


QAdvis

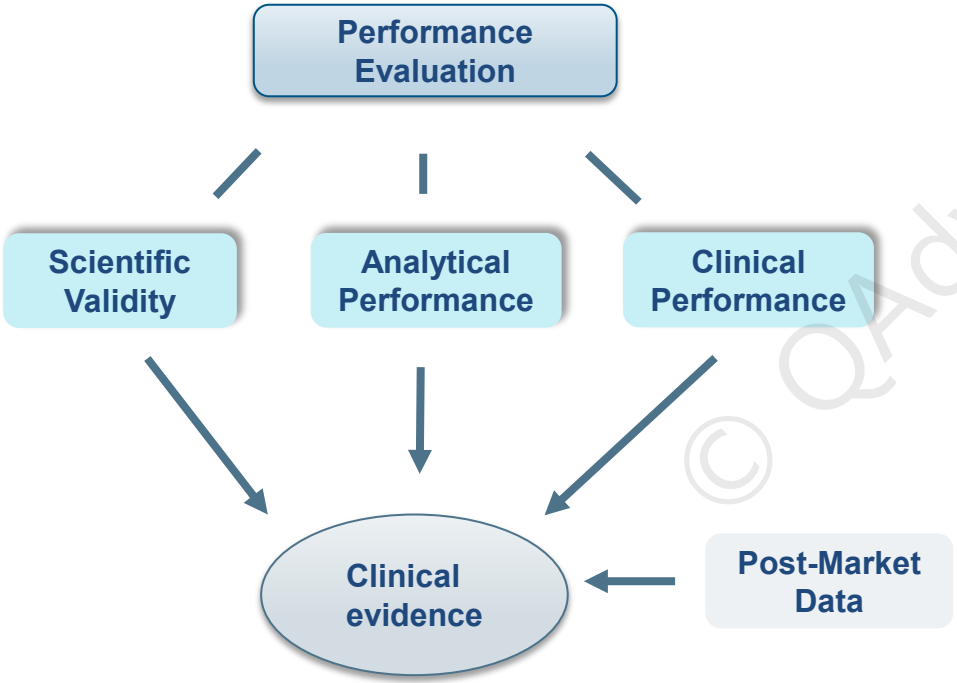
Classification rules - 7 rules and 4 classes

A. Low individual risk and low public health risk
B. Moderate individual risk and/or low public health risk
C. High individual risk and/or moderate public health risk
D. High individual risk and/or high public health risk

(IVDR Annex VIII)


Rule 1
Blood screening
High risk desease
Y
D
N
Rule 2
Blood or tissue compata-bility
Y
C
High risk blood groups
Y
D
N
Rule 3
Infection desease
Cancer testing
Companion diagnostic
Genetic testing
Congental screening
Y
C
N
Rule 4
Self testing
High risk near-patient-test
Y
C
Self test Exempted List
Y
B
N
Rule 5
Specific IVD reagents
Instruments
Specimen receptacles
Y
A
N
Rule 6
None of the other rules
Y
B
Rule 7
Controls no assigned values
Y
B

Performance evaluation - concept overview



- Intended purpose and intended use
- Assessment and analysis of data to establish or verify the scientific validity, the analytical, and, where applicable, the clinical performance of a device
- A continuous process
- Extent according to e.g. risks, device classification and intended use

(IVDR Annex XIII)

QAdvis

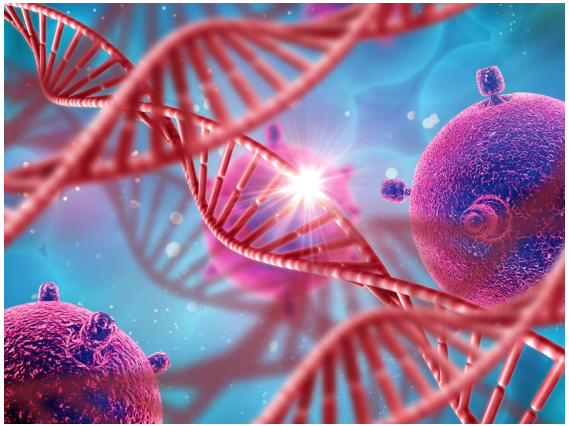
Performance evaluation – Content according to IVDR

1. Performance evaluation plan
2. Demonstration of scientific validity
3. Demonstration of analytical performance
4. Demonstration of clinical performance
5. Performance evaluation report = documentation of the clinical evidence

(IVDR Annex XIII)

QAdvis

Post-market surveillance (PMS)

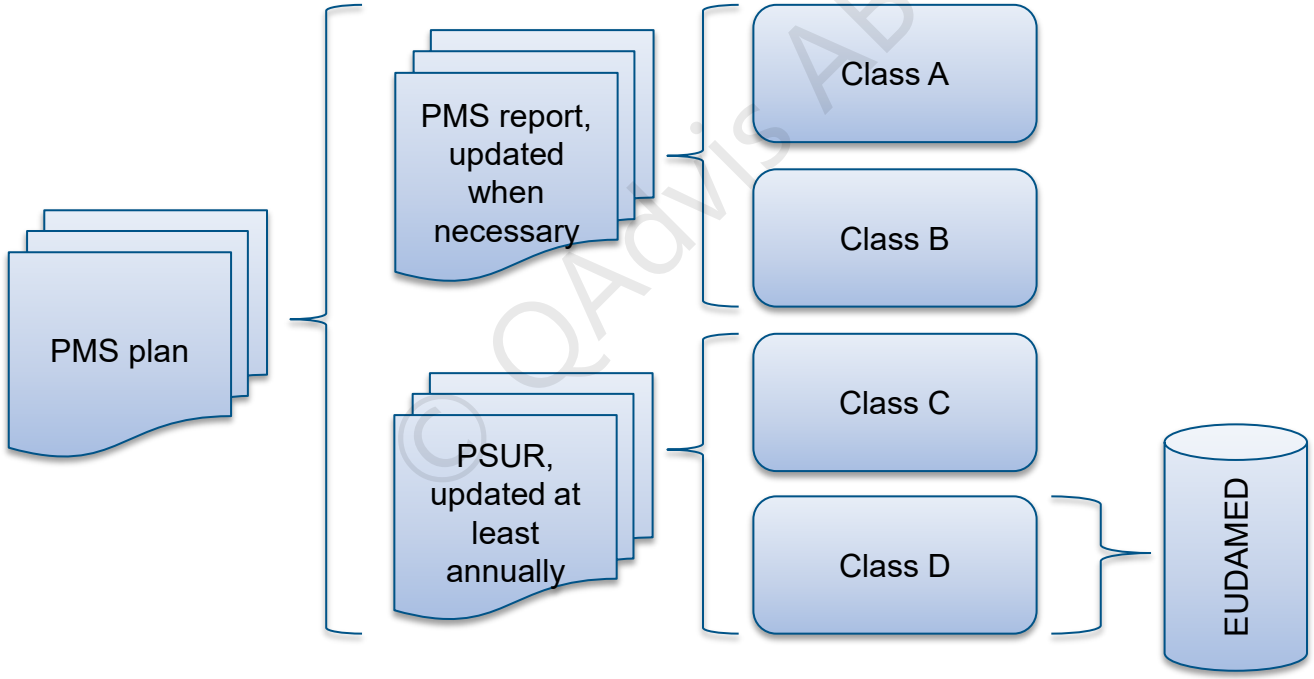


For each device the manufacturer shall

- plan,
- document,
- implement,
- maintain and
- update a post-market surveillance system
- proportionate to the risk class of the device and appropriate for the device type.

(MDR Article 83 / IVDR Article 78)

Post-market surveillance



(IVDR Article 79, 80, 81)

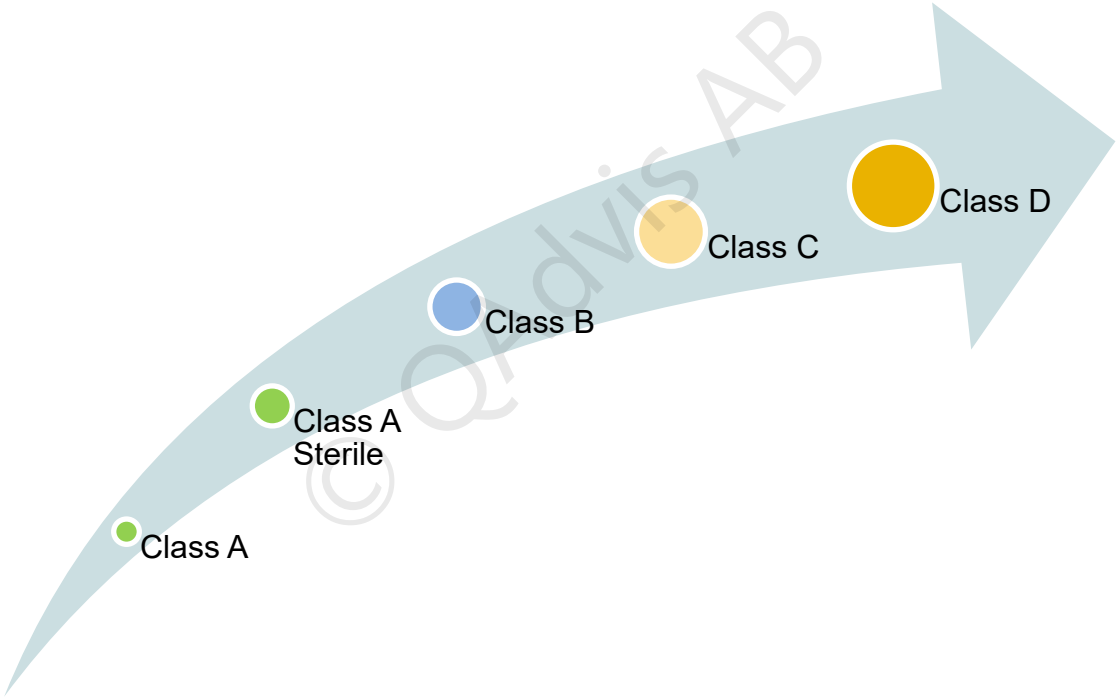
QAdvis

Conformity route

- Conformity route to be selected for each device category – different routs to chose between depending on classification and type of device
- Involvement of Notified Body differs depending on assessment route and device classification

(MDR Article 52 / IVDR Article 48)

Conformity route – involvement of Notified Body



(IVDR Article 48)

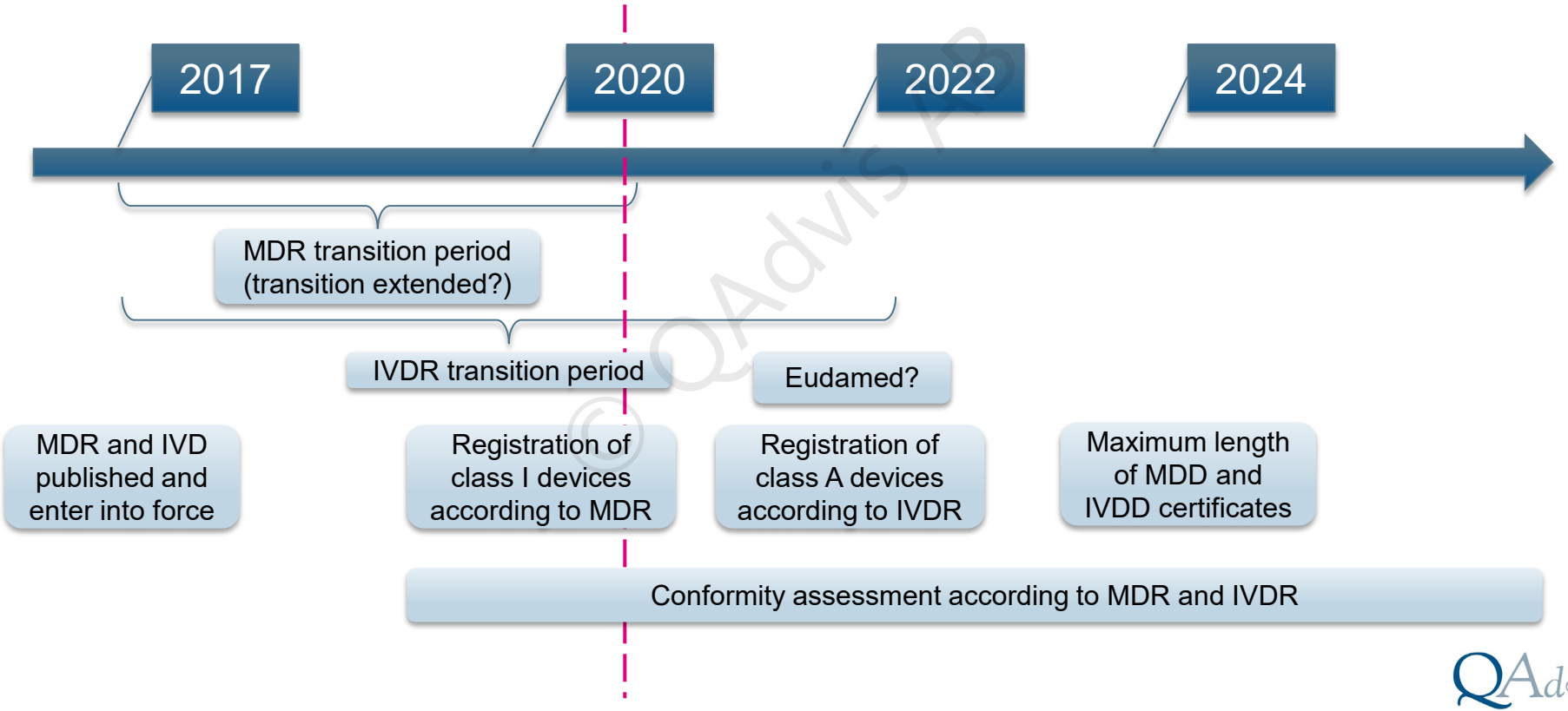
Eudamed

- European database for medical devices
- Communication between actors
- Registration of all devices by economic operators
- Accessed by
  - Economic operators
  - Competent Authority
  - Notified Body
  - The general public
- Regularly updated with post-market data and vigilance

(MDR Article 28 / IVDR Article 25)

QAdvis

Timeline



QAdvis


Your
Regulatory
Partner
6 ml
IMPLEMENTATION
QAdvis

1

Qualification and classification
Qualify the device as a medical device and based on the intended use make classification according to MDR.

Qualification and classification rational for applicable devices

2

Gap analysis and portfolio assessment
Gap analysis of device technical documentation, clinical data and quality management system.

Gap-analysis

3

Transfer strategy and time plan
Development of strategy for implementation, identification of possible conformity route, contact a notified body and creation of overall time plan.

Project plan, support in notified body contacts

4

Implementation
Detailed implementation plan, identification of resources. Execute implementation actions, development of QMS and technical documentation.

Implementation action plan as a complement to the project plan. Updated technical documentation and QMS.

5

Deploy new QMS and PRRC
Establish the role of Person Responsible for Regulatory Compliance (PRRC) in the organization. Implementation and training in new QMS procedures.

MDR and QMS training sessions. Role description and implementation in organization for PRRC

6

Technical documentation – pre-assessment
Pre-assessment of the updated technical documentation to ensure MDR requirements are covered and allow for a faster review time by the notified body.

Review report with identified proposed actions and non-conformities

7

Internal audits and mock audit
Internal audit to ensure successful implementation of MDR requirements and a mock-audit to prepare the company for the certification audit.

Audit report with identified proposed actions and non-conformities

8

Conformity assessment (class I)
Sign DoC and product registration

Conformity assessment
Notified body audit and review of technical documentation.

Support regarding response handling and non-conformities. EC-certificate – products are approved to be placed on the market.


Your
Regulatory
Partner
6 ml
LATEST UPDATES
QAdvis

NB status

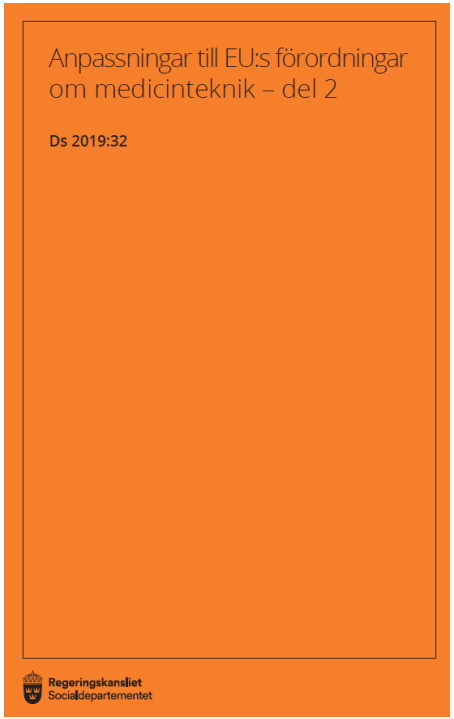
- 3 notified bodies designated under IVDR
- 12 notified bodies designated under MDR

Body type	Name	Country
NB 0086	BSI Assurance UK Ltd	United Kingdom
NB 2797	BSI Group The Netherlands B.V.	Netherlands
NB 0124	DEKRA Certification GmbH	Germany

Body type	Name	Country
NB 0086	BSI Assurance UK Ltd	United Kingdom
NB 2797	BSI Group The Netherlands B.V.	Netherlands
NB 1912	DARE!! Services B.V.	Netherlands
NB 0344	DEKRA Certification B.V.	Netherlands
NB 0124	DEKRA Certification GmbH	Germany
NB 0051	IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.	Italy
NB 0482	MEDCERT ZERTIFIZIERUNGS- UND PRÜFUNGSGESELLSCHAFT FÜR DIE MEDIZIN GMBH	Germany
NB 0197	TÜV Rheinland LGA Products GmbH	Germany
NB 0123	TÜV SÜD Product Service GmbH Zertifizierstellen	Germany

(https://ec.europa.eu/growth/tools-databases/nando/index.cfm)

Ds 2019:32



- Language requirements
- National registration
- Fees
- Sanctions and penalties
- Clinical trials
- Market surveillance

QAdvis

Implementing acts

- List of codes and corresponding types of devices for notified bodies
- UDI issuing entities

(https://eur-lex.europa.eu/homepage.html)

MDCG guidelines – need to be controlled regularly

- UDI guidance documents
- Eudamed registration
- Qualification and classification of software
- Guidance on cybersecurity for medical devices
- Guidance on Clinical Evaluation (MDR) / Performance Evaluation (IVDR) of Medical Device Software

(https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en)

QAdvis

Corrigendum MDR and IVDR

Corrigenda to the medical devices regulations

- Corrigendum of 27 December 2019 to Regulation (EU) 2017/745 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Directives 90/385/EEC and 93/42/EEC
- Corrigendum of 27 December 2019 to Regulation (EU) 2017/746 on in vitro diagnostic medical devices, repealing Directive 98/79/EC and Commission decision 2010/227/EU
- Corrigendum of 5 May 2019 to Regulation (EU) 2017/745 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Directives 90/385/EEC and 93/42/EEC
- Corrigendum of 5 May 2019 to Regulation (EU) 2017/746 on in vitro diagnostic medical devices, repealing Directive 98/79/EC and Commission decision 2010/227/EU

(https://ec.europa.eu/growth/sectors/medical-devices/new-regulations_en)

QAdvis

Concerns

- A lot of work for Notified Bodies and Competent Authorities
- Lack of reference laboratories (will be designated Q1/Q2 2020 acc to rolling plan, 15/4)
- Decreasing number of Notified Bodies
- More devices and manufacturers in need of a Notified Body
- EUDAMED is delayed with 2 years
- Common Specifications necessary for implementation not published in time
- Necessary Implementing Acts not ready in time

What is going on?

- Notified Bodies designations
- Medical Device Coordination Group (MDCG) work ongoing
- Harmonization of standards
- Implementation in national law
- EU work groups
  - Expert committee and sub-groups

Conclusions

- A lot of work – start now!
- No grandfathering:

  Not ready in time = products can not be placed on the market
- Stricter requirements on all players (Authorities, Notified Bodies and Manufacturers)
- Sufficient clinical data necessary
- Many products will be up-classified

QAdvis services

- Courses
  - IVDR / MDR
  - Risk management,
  - SW risk management
  - ISO 13485:2016
- Product specific workshop
- Internal trainings
- GAP analysis and implementation plan
- Quality Management System
- Auditing
- Risk management
- Clinical evaluation

Utvärdering